IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE AURYXIA (FERRIC CITRATE) PATENT LITIG.	MDL No. 19-2896-LPS **This document relates to C.A. No. 18-1968**
KERYX BIOPHARMACEUTICALS, INC., PANION & BF BIOTECH, INC. and CHEN HSING HSU, *Plaintiffs-Counterclaim Defendants*, v. LUPIN LTD. and LUPIN ATLANTIS HOLDINGS SA, *Defendants-Counterclaim Plaintiffs*.	C.A. No. 18-1968 (LPS)

FIRST AMENDED COMPLAINT FOR PATENT INFRINGMENT

Plaintiffs Keryx Biopharmaceuticals, Inc. ("Keryx"), Panion & BF Biotech, Inc. ("Panion") and Chen Hsing Hsu ("Dr. Hsu") (collectively, "Plaintiffs"), by their undersigned attorneys, for their First Amended Complaint against Defendants Lupin Ltd. ("Lupin Ltd.") and Lupin Atlantis Holdings SA ("Lupin Atlantis") (collectively "Lupin" or "Defendants"), allege as follows:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, et seq., as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, arising from Lupin's submission of Abbreviated New Drug Application ("ANDA") No. 212537

("Lupin's ANDA") to the United States Food and Drug Administration ("FDA") seeking approval to commercially market generic versions of Keryx's AURYXIA® (Ferric Citrate) Tablets ("Lupin's Proposed Product") prior to the expiration of United States Patent Nos. 5,753,706 (the "'706 patent"); 7,767,851 (the "'851 patent"); 8,093,423 (the "'423 patent"); 8,299,298 (the "'298 patent"); 8,338,642 (the "'642 patent"); 8,609,896 (the "'896 patent"); 8,754,257 (the "'257 patent"); 8,754,258 (the "'258 patent"); 8,846,976 (the "'976 patent"); 8,901,349 (the "'349 patent"); 9,050,316 (the "'316 patent"); 9,328,133 (the "'133 patent"); 9,757,416 (the "'416 patent"); 9,387,191 (the "'191 patent"); and 10,300,039 (the "'039 patent") (collectively, the "patents-in-suit"), owned by Plaintiffs.

2. Plaintiffs brought a related action for patent infringement against Lupin Ltd. in this Court on May 10, 2019 arising from Lupin's submission of a different ANDA—ANDA No. 209693. That action is captioned *Keryx Biopharmaceuticals, Inc., Panion & BF Biotech, Inc. and Chen Hsing Hsu v. Lupin Ltd.*, No. 19-884 (D. Del.).

The Parties

3. Plaintiff Keryx is a corporation organized and existing under the laws of Delaware with a principal place of business at One Marina Park Drive, Twelfth Floor, Boston, Massachusetts 02210.

4. Plaintiff Panion is a corporation organized and existing under the laws of Taiwan, with its principal place of business at 16F No. 3, Yuanqu Street, Nangang District, Taipei, Taiwan.

5. Plaintiff Dr. Hsu is an individual residing at 2244 Hot Oak Ridge Street, Las Vegas, Nevada 89134.

6. On information and belief, Lupin Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex Bandra (E), Mumbai, 400 051, India.

7. On information and belief, Lupin Atlantis is a corporation organized and existing under the laws of Switzerland, having its principal place of business at Landis+ Gyr-Strasse 1, 6300 Zug, Switzerland. On information and belief, Lupin Atlantis is a wholly-owned subsidiary of Lupin Ltd.

8. On information and belief, Lupin is in the business of marketing, distributing, and/or selling pharmaceutical drugs, including generic pharmaceutical drugs manufactured by Lupin, throughout the United States, including in this Judicial District.

9. On information and belief, Lupin Atlantis, in conjunction with or under the direction of Lupin Ltd., developed Lupin's Proposed Product and/or prepared ANDA No. 212537 for submission. On information and belief, Lupin Ltd. is the owner of Drug Master File ("DMF") No. 30347 that covers the active pharmaceutical ingredient used in Lupin's Proposed Product. On information and belief, upon receiving approval of ANDA No. 212537, Lupin Atlantis, in conjunction with or under the direction of Lupin Ltd., will manufacture, sell, offer to sell, and/or import Lupin's Proposed Product in the United States, including in this district.

The Patents-in-Suit

10. On May 19, 1998, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '706 patent, entitled, "Methods for Treating Renal Failure." The '706 patent is assigned to Dr. Hsu. Keryx is the exclusive licensee of all rights in the '706 patent that are relevant to this litigation. A copy of the '706 patent is attached hereto as Exhibit A.

11. On August 3, 2010, the USPTO duly and lawfully issued the '851 patent, entitled, "Ferric Organic Compounds, Uses Thereof and Methods of Making Same." The '851 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the '851 patent that are relevant to this litigation. A copy of the '851 patent is attached hereto as Exhibit B.

12. On January 10, 2012, the USPTO duly and lawfully issued the '423 patent, entitled, "Pharmaceutical-Grade Ferric Organic Compounds, Uses Thereof and Method of Making Same." The '423 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the '423 patent that are relevant to this litigation. A copy of the '423 patent is attached hereto as Exhibit C.

13. On October 30, 2012, the USPTO duly and lawfully issued the '298 patent, entitled, "Pharmaceutical-Grade Ferric Organic Compounds, Uses Thereof and Method of Making Same." The '298 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the '298 patent that are relevant to this litigation. A copy of the '298 patent is attached hereto as Exhibit D.

14. On December 25, 2012, the USPTO duly and lawfully issued the '642 patent, entitled, "Ferric Organic Compounds, Uses Thereof and Methods of Making Same." The '642 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the '642 patent that are relevant to this litigation. A copy of the '642 patent is attached hereto as Exhibit E.

15. On December 17, 2013, the USPTO duly and lawfully issued the '896 patent, entitled, "Ferric Organic Compounds, Uses Thereof and Methods of Making Same." The '896 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the '896 patent that are relevant to this litigation. A copy of the '896 patent is attached hereto as Exhibit F.

16. On June 17, 2014, the USPTO duly and lawfully issued the '257 patent, entitled, "Pharmaceutical-Grade Ferric Organic Compounds, Uses Thereof and Methods of Making Same." The '257 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the '257 patent that are relevant to this litigation. A copy of the '257 patent is attached hereto as Exhibit G.

17. On June 17, 2014, the USPTO duly and lawfully issued the '258 patent, entitled, "Ferric Organic Compounds, Uses Thereof and Methods of Making Same." The '258 patent is

assigned to Panion. Keryx is the exclusive licensee of all rights in the ’258 patent that are relevant to this litigation. A copy of the ’258 patent is attached hereto as Exhibit H.

18. On September 30, 2014, the USPTO duly and lawfully issued the ’976 patent, entitled, “Ferric Organic Compounds, Uses Thereof and Methods of Making Same.” The ’976 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the ’976 patent that are relevant to this litigation. A copy of the ’976 patent is attached hereto as Exhibit I.

19. On December 2, 2014, the USPTO duly and lawfully issued the ’349 patent, entitled, “Ferric Organic Compounds, Uses Thereof and Methods of Making Same.” The ’349 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the ’349 patent that are relevant to this litigation. A copy of the ’349 patent is attached hereto as Exhibit J.

20. On June 9, 2015, the USPTO duly and lawfully issued the ’316 patent, entitled, “Pharmaceutical-Grade Ferric Organic Compounds, Uses Thereof and Methods of Making Same.” The ’316 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the ’316 patent that are relevant to this litigation. A copy of the ’316 patent is attached hereto as Exhibit K.

21. On May 3, 2016, the USPTO duly and lawfully issued the ’133 patent, entitled, “Ferric Organic Compounds, Uses Thereof and Methods of Making Same.” The ’133 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the ’133 patent that are relevant to this litigation. A copy of the ’133 patent is attached hereto as Exhibit L.

22. On September 12, 2017, the USPTO duly and lawfully issued the ’416 patent, entitled “Pharmaceutical-Grade Ferric Organic Compounds, Uses Thereof and Methods of Making Same.” The ’416 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the ’416 patent that are relevant to this litigation. A copy of the ’416 patent is attached hereto as Exhibit M.

23. On July 12, 2016, the USPTO duly and lawfully issued the '191 patent, entitled, "Ferric Citrate Dosage Forms." The '191 patent is assigned to Keryx. A copy of the '191 patent is attached hereto as Exhibit N.

24. On May 28, 2019 the USPTO duly and lawfully issued the '039 patent, entitled "Ferric Citrate Dosage Forms." The '039 patent is assigned to Keryx. A copy of the '039 patent is attached hereto as Exhibit O.

The AURYXIA® (Ferric Citrate) Drug Product

25. Keryx holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for ferric citrate, 210 mg tablets (NDA No. 205874), which it sells under the trade name AURYXIA®. AURYXIA® is an orally available, absorbable, iron-based medicine. AURYXIA® is FDA-approved for the control of serum phosphorus levels in adult patients with chronic kidney disease ("CKD") on dialysis, and for the treatment of iron deficiency anemia in adult patients with CKD not on dialysis. The claims of the patents-in-suit cover, *inter alia,* novel forms of ferric citrate, methods of controlling phosphate retention, methods of decreasing serum calcium levels, and methods of treating hyperphosphatemia.

26. Pursuant to 21 U.S.C. §§ 355(b)(1) and 355(c)(2) and attendant FDA regulations, the patents-in-suit, with the exception of the '039 patent, were listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to AURYXIA® before this action was filed.

27. Pursuant to 21 U.S.C. § 355(c)(2) and attendant FDA regulations, the '039 patent was submitted for listing in the Orange Book with respect to AURYXIA® on June 24, 2019.

Jurisdiction and Venue

28. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

29. On information and belief, Lupin Atlantis, with the participation of Lupin Ltd., has submitted, caused to be submitted, or aided and abetted in the preparation of Lupin's ANDA. On information and belief, upon FDA approval of Lupin's ANDA, Lupin Atlantis, with the participation of Lupin Ltd., intends to commercially manufacture, import, market, offer for sale, and/or sell Lupin's Proposed Product throughout the United States including in this district.

30. This Court has personal jurisdiction over Lupin Atlantis by virtue of, *inter alia,* its systematic and continuous contacts with the State of Delaware. On information and belief, Lupin Atlantis purposefully has conducted and continues to conduct business, directly or through its parent, subsidiaries, affiliates and/or agents, including Lupin Ltd., in this Judicial District, and this Judicial District is a likely destination of Lupin's Proposed Product.

31. This Court has personal jurisdiction over Lupin Ltd. by virtue of, *inter alia*, its systematic and continuous contacts with the State of Delaware.

32. This Court has personal jurisdiction over Lupin because Lupin has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with the State of Delaware. On information and belief, Lupin regularly and continuously transacts business within Delaware, including by making pharmaceutical products for sale in Delaware and selling pharmaceutical products in Delaware. On information and belief, Lupin derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware. On information and belief, Lupin derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this Judicial District.

33. On information and belief, Lupin intends to engage in a future course of conduct that includes acts of patent infringement in Delaware. These acts will lead to foreseeable harm and injury to Plaintiffs in Delaware and in this Judicial District. For example, on information and belief, Lupin will work towards the regulatory approval, manufacturing, use, importation, marketing, offer for sale, sale, and distribution of generic pharmaceutical products, including Lupin's Proposed Product, throughout the United States, including in Delaware and in this Judicial District, prior to the expiration of the patents-in-suit.

34. On information and belief, Lupin Atlantis was sued for patent infringement in this Judicial District, did not contest personal jurisdiction in this Judicial District, and availed itself of this Judicial District through the assertion of counterclaims in at least the following cases: *Vifor Fresenius Medical Care Renal Pharma Ltd., et al. v. Lupin Atlantis Holdings SA, et al.,* No. 18-390-LPS (D.Del.), and *Teva Branded Pharmaceutical Products R&D, Inc., et al. v. Lupin Atlantis Holdings SA, et al.,* No. 17-307-GMS (D.Del.).

35. On information and belief, Lupin Ltd. was sued for patent infringement in this Judicial District, did not contest personal jurisdiction in this Judicial District, and availed itself of this Judicial District through the assertion of counterclaims in at least the following case: *Anacor Pharmaceuticals, Inc. v. Lupin Ltd., et al.,* No. 18-1606-LPS (D.Del.).

36. On information and belief, Lupin Atlantis was previously sued in this Judicial District and did not challenge venue in at least the following cases: *Vifor Fresenius Medical Care Renal Pharma Ltd., et al. v. Lupin Atlantis Holdings SA, et al.,* No. 18-390 (LPS) (D.Del.), and *Teva Branded Pharmaceutical Products R&D, Inc., et al. v. Lupin Atlantis Holdings SA, et al.,* No. 17-307-GMS (D.Del.).

37. On information and belief, Lupin Ltd. was previously sued in this Judicial District and did not challenge venue in at least the following cases: *Teva Branded Pharmaceutical Products R&D, Inc., et al. v. Lupin Atlantis Holdings SA, et al.,* No. 17-307-GMS (D.Del.), and *Anacor Pharmaceuticals, Inc. v. Lupin Ltd., et al.,* No. 18-1606-LPS (D.Del.).

38. In the alternative, this Court has personal jurisdiction over Lupin Ltd. and Lupin Atlantis because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Plaintiffs' claims arise under federal law; (b) Lupin Ltd. and Lupin Atlantis are foreign defendants not subject to general personal jurisdiction in the courts of any state; and (c) Lupin Ltd. and Lupin Atlantis have sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs to the FDA and/or manufacturing, importing, offering to sell, and/or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Lupin Ltd. and Lupin Atlantis satisfies due process.

39. Venue is proper for Lupin Ltd. and Lupin Atlantis pursuant to 28 U.S.C. §§ 1391(c)(3) and 1400(b) including because, *inter alia,* Lupin Ltd. and Lupin Atlantis are foreign corporations.

Acts Giving Rise to This Suit

40. Pursuant to Section 505 of the FFDCA, Lupin Atlantis filed Lupin's ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Lupin's Proposed Product before the patents-in-suit expire.

41. On information and belief, following FDA approval of Lupin's ANDA, Lupin will manufacture, use, offer to sell, or sell Lupin's Proposed Product throughout the United States, or import such generic products into the United States.

42. On information and belief, in connection with the filing of its ANDA as described above, Lupin provided a written certification to the FDA, as called for by Section 505 of the

FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), ("Lupin's Paragraph IV Certification") alleging that the claims of the patents-in-suit, other than the '039 patent, are invalid, unenforceable, and/or will not be infringed by the activities described in Lupin's ANDA.

43. No earlier than October 30, 2018, Lupin sent written notice of its Paragraph IV Certification to Plaintiffs ("Lupin's First Notice Letter"). Lupin's First Notice Letter alleged that the claims of the patents-in-suit, excluding the '039 patent, are invalid and/or will not be infringed by the activities described in Lupin's ANDA. Lupin's First Notice Letter also informed Plaintiffs that Lupin seeks approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of Lupin's Proposed Product before the patents-in-suit, excluding the '039 patent, expire.

44. In Lupin's First Notice Letter, Lupin offered to provide access to certain confidential information and materials within Lupin's ANDA pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III). Lupin's offer of confidential access was conditioned on terms identified in Lupin's First Notice Letter. The terms and conditions of Lupin's offer of confidential access were unreasonable and beyond those that would apply under a protective order. The restrictions Lupin has placed on access to its ANDA contravene 21 U.S.C. § 355(j)(5)(C)(i)(III). The parties did not reach an agreement on the terms of such confidential access. To date, Lupin has not provided any portion of its ANDA to Plaintiffs.

45. The Complaint in this action was filed before expiration of the forty-five days from the date Plaintiffs received Lupin's First Notice Letter.

46. No earlier than July 30, 2019, Lupin sent written notice of another Paragraph IV Certification to Plaintiffs ("Lupin's Second Notice Letter"). Lupin's Second Notice Letter alleged that the claims of the '039 patent are invalid and/or will not be infringed by the activities described

in Lupin's ANDA. Lupin's Second Notice Letter also informed Plaintiffs that Lupin seeks approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of Lupin's Proposed Product before the '039 patent expires. Plaintiffs received Lupin's Second Notice Letter no earlier than July 31, 2019.

47. In Lupin's Second Notice Letter, Lupin offered to provide access to certain confidential information and materials within Lupin's ANDA pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III). Lupin's offer of confidential access was conditioned on terms identified in Lupin's Second Notice Letter. The terms and conditions of Lupin's offer of confidential access were unreasonable and beyond those that would apply under a protective order. The restrictions Lupin sought to impose on access to its ANDA contravened 21 U.S.C. § 355(j)(5)(C)(i)(III). To date, Lupin has not provided any portion of its ANDA to Plaintiffs.

48. Plaintiffs sought leave to file this First Amended Complaint, alleging infringement of the '039 patent, before expiration of the forty-five days from the date Plaintiffs received Lupin's Second Notice Letter.

Count I: Infringement of the '706 Patent

49. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

50. Lupin's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Lupin's Proposed Product, prior to the expiration of the '706 patent, constitutes infringement of one or more of the claims of the '706 patent under 35 U.S.C. § 271(e)(2)(A), including at least claims 1, 6, and 9.

51. A justiciable controversy exists between the parties hereto as to the infringement of the '706 patent.

52. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will infringe one or more claims of the '706 patent under 35 U.S.C. § 271(a), including at least claim 6, by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in the United States.

53. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will induce infringement of one or more claims of the '706 patent under 35 U.S.C. § 271(b), including at least claims 1 and 9, by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in the United States. On information and belief, upon FDA approval of Lupin's ANDA, Lupin will intentionally encourage acts of direct infringement with knowledge of the '706 patent and with knowledge that its acts are encouraging infringement.

54. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will contributorily infringe one or more claims of the '706 patent under 35 U.S.C. § 271(c), including at least claims 1 and 9, by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in the United States. On information and belief, Lupin knew and knows that Lupin's Proposed Product is designed for a use that infringes one or more claims of the '706 patent, and Lupin's Proposed Product lacks a substantial non-infringing use.

55. Plaintiffs will be substantially and irreparably damaged and harmed if Lupin's infringement of the '706 patent is not enjoined.

56. Plaintiffs do not have an adequate remedy at law.

57. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

Count II: Infringement of the '851 Patent

58. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

59. Lupin's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Lupin's Proposed Product, prior to the expiration of the '851 patent, constitutes infringement of one or more of the claims of the '851 patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

60. A justiciable controversy exists between the parties hereto as to the infringement of the '851 patent.

61. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will infringe one or more claims of the '851 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in the United States.

62. Plaintiffs will be substantially and irreparably damaged and harmed if Lupin's infringement of the '851 patent is not enjoined.

63. Plaintiffs do not have an adequate remedy at law.

64. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

Count III: Infringement of the '423 Patent

65. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

66. Lupin's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Lupin's Proposed Product, prior to the expiration of the '423 patent, constitutes infringement of one or more of the claims of the '423 patent under 35 U.S.C. § 271(e)(2)(A), including at least claims 1-7.

67. A justiciable controversy exists between the parties hereto as to the infringement of the '423 patent.

68. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will induce infringement of one or more claims of the '423 patent under 35 U.S.C. § 271(b), including at least claims 1-7, by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in the United States. On information and belief, upon FDA approval of Lupin's ANDA, Lupin will intentionally encourage acts of direct infringement with knowledge of the '423 patent and with knowledge that its acts are encouraging infringement.

69. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will contributorily infringe one or more claims of the '423 patent under 35 U.S.C. § 271(c), including at least claims 1-7, by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in the United States. On information and belief, Lupin knew and knows that Lupin's Proposed Product is designed for a use that infringes one or more claims of the '423 patent, and Lupin's Proposed Product lacks a substantial non-infringing use.

70. Plaintiffs will be substantially and irreparably damaged and harmed if Lupin's infringement of the '423 patent is not enjoined.

71. Plaintiffs do not have an adequate remedy at law.

72. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

Count IV: Infringement of the '298 Patent

73. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

74. Lupin's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Lupin's Proposed Product, prior to the expiration of the '298 patent, constitutes infringement of one or more of the claims of the '298 patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

75. A justiciable controversy exists between the parties hereto as to the infringement of the ’298 patent.

76. Unless enjoined by this Court, upon FDA approval of Lupin’s ANDA, Lupin will infringe one or more claims of the ’298 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Lupin’s Proposed Product in the United States.

77. Plaintiffs will be substantially and irreparably damaged and harmed if Lupin’s infringement of the ’298 patent is not enjoined.

78. Plaintiffs do not have an adequate remedy at law.

79. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys’ fees under 35 U.S.C. § 285.

Count V: Infringement of the ’642 Patent

80. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

81. Lupin’s submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Lupin’s Proposed Product, prior to the expiration of the ’642 patent, constitutes infringement of one or more of the claims of the ’642 patent under 35 U.S.C. § 271(e)(2)(A), including at least claims 1, 8-10, and 17-18.

82. A justiciable controversy exists between the parties hereto as to the infringement of the ’642 patent.

83. Unless enjoined by this Court, upon FDA approval of Lupin’s ANDA, Lupin will infringe one or more claims of the ’642 patent under 35 U.S.C. § 271(a), including at least claims 1 and 10, by making, using, offering to sell, selling, and/or importing Lupin’s Proposed Product in the United States.

84. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will induce infringement of one or more claims of the '642 patent under 35 U.S.C. § 271(b), including at least claims 8-9 and 17-18, by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in the United States. On information and belief, upon FDA approval of Lupin's ANDA, Lupin will intentionally encourage acts of direct infringement with knowledge of the '642 patent and with knowledge that its acts are encouraging infringement.

85. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will contributorily infringe one or more claims of the '642 patent under 35 U.S.C. § 271(c), including at least claims 8-9 and 17-18, by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in the United States. On information and belief, Lupin knew and knows that Lupin's Proposed Product is designed for a use that infringes one or more claims of the '642 patent, and Lupin's Proposed Product lacks a substantial non-infringing use.

86. Plaintiffs will be substantially and irreparably damaged and harmed if Lupin's infringement of the '642 patent is not enjoined.

87. Plaintiffs do not have an adequate remedy at law.

88. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

Count VI: Infringement of the '896 Patent

89. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

90. Lupin's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Lupin's Proposed Product, prior to the expiration of the '896 patent, constitutes infringement of one or more of the claims of the '896 patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

91. A justiciable controversy exists between the parties hereto as to the infringement of the ’896 patent.

92. Unless enjoined by this Court, upon FDA approval of Lupin’s ANDA, Lupin will infringe one or more claims of the ’896 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Lupin’s Proposed Product in the United States.

93. Plaintiffs will be substantially and irreparably damaged and harmed if Lupin’s infringement of the ’896 patent is not enjoined.

94. Plaintiffs do not have an adequate remedy at law.

95. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys’ fees under 35 U.S.C. § 285.

Count VII: Infringement of the ’257 Patent

96. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

97. Lupin’s submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Lupin’s Proposed Product, prior to the expiration of the ’257 patent, constitutes infringement of one or more of the claims of the ’257 patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

98. A justiciable controversy exists between the parties hereto as to the infringement of the ’257 patent.

99. Unless enjoined by this Court, upon FDA approval of Lupin’s ANDA, Lupin will infringe one or more claims of the ’257 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Lupin’s Proposed Product in the United States.

100. Plaintiffs will be substantially and irreparably damaged and harmed if Lupin's infringement of the '257 patent is not enjoined.

101. Plaintiffs do not have an adequate remedy at law.

102. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

Count VIII: Infringement of the '258 Patent

103. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

104. Lupin's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Lupin's Proposed Product, prior to the expiration of the '258 patent, constitutes infringement of one or more of the claims of the '258 patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

105. A justiciable controversy exists between the parties hereto as to the infringement of the '258 patent.

106. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will infringe one or more claims of the '258 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in the United States.

107. Plaintiffs will be substantially and irreparably damaged and harmed if Lupin's infringement of the '258 patent is not enjoined.

108. Plaintiffs do not have an adequate remedy at law.

109. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

Count IX: Infringement of the '976 Patent

110. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

111. Lupin's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Lupin's Proposed Product, prior to the expiration of the '976 patent, constitutes infringement of one or more of the claims of the '976 patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

112. A justiciable controversy exists between the parties hereto as to the infringement of the '976 patent.

113. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will induce infringement of one or more claims of the '976 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in the United States. On information and belief, upon FDA approval of Lupin's ANDA, Lupin will intentionally encourage acts of direct infringement with knowledge of the '976 patent and with knowledge that its acts are encouraging infringement.

114. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will contributorily infringe one or more claims of the '976 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in the United States. On information and belief, Lupin knew and knows that Lupin's Proposed Product is designed for a use that infringes one or more claims of the '976 patent, and Lupin's Proposed Product lacks a substantial non-infringing use.

115. Plaintiffs will be substantially and irreparably damaged and harmed if Lupin's infringement of the '976 patent is not enjoined.

116. Plaintiffs do not have an adequate remedy at law.

117. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

Count X: Infringement of the '349 Patent

118. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

119. Lupin's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Lupin's Proposed Product, prior to the expiration of the '349 patent, constitutes infringement of one or more of the claims of the '349 patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

120. A justiciable controversy exists between the parties hereto as to the infringement of the '349 patent.

121. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will induce infringement of one or more claims of the '349 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in the United States. On information and belief, upon FDA approval of Lupin's ANDA, Lupin will intentionally encourage acts of direct infringement with knowledge of the '349 patent and with knowledge that its acts are encouraging infringement.

122. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will contributorily infringe one or more claims of the '349 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in the United States. On information and belief, Lupin knew and knows that Lupin's Proposed Product is designed for a use that infringes one or more claims of the '349 patent, and Lupin's Proposed Product lacks a substantial non-infringing use.

123. Plaintiffs will be substantially and irreparably damaged and harmed if Lupin's infringement of the '349 patent is not enjoined.

124. Plaintiffs do not have an adequate remedy at law.

125. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

Count XI: Infringement of the '316 Patent

126. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

127. Lupin's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Lupin's Proposed Product, prior to the expiration of the '316 patent, constitutes infringement of one or more of the claims of the '316 patent under 35 U.S.C. § 271(e)(2)(A), including at least claims 1 and 12.

128. A justiciable controversy exists between the parties hereto as to the infringement of the '316 patent.

129. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will induce infringement of one or more claims of the '316 patent under 35 U.S.C. § 271(b), including at least claims 1 and 12, by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in the United States. On information and belief, upon FDA approval of Lupin's ANDA, Lupin will intentionally encourage acts of direct infringement with knowledge of the '316 patent and with knowledge that its acts are encouraging infringement.

130. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will contributorily infringe one or more claims of the '316 patent under 35 U.S.C. § 271(c), including at least claims 1 and 12, by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in the United States. On information and belief, Lupin knew and knows that

Lupin's Proposed Product is designed for a use that infringes one or more claims of the '316 patent, and Lupin's Proposed Product lacks a substantial non-infringing use.

131. Plaintiffs will be substantially and irreparably damaged and harmed if Lupin's infringement of the '316 patent is not enjoined.

132. Plaintiffs do not have an adequate remedy at law.

133. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

Count XII: Infringement of the '133 Patent

134. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

135. Lupin's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Lupin's Proposed Product, prior to the expiration of the '133 patent, constitutes infringement of one or more of the claims of the '133 patent under 35 U.S.C. § 271(e)(2)(A), including at least claims 1, 8-10, and 17-18.

136. A justiciable controversy exists between the parties hereto as to the infringement of the '133 patent.

137. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will infringe one or more claims of the '133 patent under 35 U.S.C. § 271(a), including at least claims 1 and 10, by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in the United States.

138. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will induce infringement of one or more claims of the '133 patent under 35 U.S.C. § 271(b), including at least claims 8-9 and 17-18, by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in the United States. On information and belief, upon FDA approval of Lupin's

ANDA, Lupin will intentionally encourage acts of direct infringement with knowledge of the '133 patent and with knowledge that its acts are encouraging infringement.

139. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will contributorily infringe one or more claims of the '133 patent under 35 U.S.C. § 271(c), including at least claims 8-9 and 17-18, by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in the United States. On information and belief, Lupin knew and knows that Lupin's Proposed Product is designed for a use that infringes one or more claims of the '133 patent, and Lupin's Proposed Product lacks a substantial non-infringing use.

140. Plaintiffs will be substantially and irreparably damaged and harmed if Lupin's infringement of the '133 patent is not enjoined.

141. Plaintiffs do not have an adequate remedy at law.

142. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

Count XIII: Infringement of the '191 Patent

143. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

144. Lupin's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Lupin's Proposed Product, prior to the expiration of the '191 patent, constitutes infringement of one or more of the claims of the '191 patent under 35 U.S.C. § 271(e)(2)(A), including at least claims 1, 6, 11 and 16.

145. A justiciable controversy exists between the parties hereto as to the infringement of the '191 patent.

146. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will infringe one or more claims of the '191 patent under 35 U.S.C. § 271(a), including at least claims

1, 6, 11 and 16, by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in the United States.

147. Plaintiffs will be substantially and irreparably damaged and harmed if Lupin's infringement of the '191 patent is not enjoined.

148. Plaintiffs do not have an adequate remedy at law.

149. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

Count XIV: Infringement of the '416 Patent

150. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

151. Lupin's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Lupin's Proposed Product, prior to the expiration of the '416 patent, constitutes infringement of one or more of the claims of the '416 patent under 35 U.S.C. § 271(e)(2)(A), including at least claims 1, 12, 23, and 30.

152. A justiciable controversy exists between the parties hereto as to the infringement of the '416 patent.

153. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will induce infringement of one or more claims of the '416 patent under 35 U.S.C. § 271(b), including at least claims 1, 12, 23, and 30, by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in the United States. On information and belief, upon FDA approval of Lupin's ANDA, Lupin will intentionally encourage acts of direct infringement with knowledge of the '416 patent and with knowledge that its acts are encouraging infringement.

154. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will contributorily infringe one or more claims of the '416 patent under 35 U.S.C. § 271(c), including at

least claims 1, 12, 23 and 30, by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in the United States. On information and belief, Lupin knew and knows that Lupin's Proposed Product is designed for a use that infringes one or more claims of the '416 patent, and Lupin's Proposed Product lacks a substantial non-infringing use.

155. Plaintiffs will be substantially and irreparably damaged and harmed if Lupin's infringement of the '416 patent is not enjoined.

156. Plaintiffs do not have an adequate remedy at law.

157. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

Count XIII: Infringement of the '039 Patent

158. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

159. Lupin's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Lupin's Proposed Product, prior to the expiration of the '039 patent, constitutes infringement of one or more of the claims of the '039 patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, such as, for example, claim 1.

160. A justiciable controversy exists between the parties hereto as to the infringement of the '039 patent.

161. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will actively induce infringement of one or more claims of the '039 patent under 35 U.S.C. § 271(b), such as, for example, claims 1, 4, 5, 8, 11, 14 and 15, by encouraging others, including but not limited to healthcare providers and patients, to use, offer for sale, sell, or import Lupin's Proposed Product in the United States. On information and belief, upon FDA approval of Lupin's ANDA,

Lupin will intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '039 patent and with knowledge that its acts are encouraging infringement.

162. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will contributorily infringe one or more claims of the '039 patent under 35 U.S.C. § 271(c), such as, for example, claims 1, 4, 5, 8, 11, 14 and 15, by offering to sell, selling, and/or importing Lupin's Proposed Product in the United States. Lupin's Proposed Product is a material for use in practicing methods claims in the '039 patent that constitutes a material part of those claims' inventions. On information and belief, Lupin knew and knows that Lupin's Proposed Product is especially made or adapted for use in infringing one or more claims of the '039 patent, and that Lupin's Proposed Product is not a staple article or commodity of commerce with a substantial non-infringing use.

163. Plaintiffs will be substantially and irreparably damaged and harmed if Lupin's infringement of the '039 patent is not enjoined.

164. Plaintiffs do not have an adequate remedy at law.

165. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment that Lupin has infringed the patents-in-suit by submitting ANDA No. 212537 to the FDA;

B. A Judgment that Lupin's commercial manufacture, use, offer to sell, sale, or importation Lupin's Proposed Product will infringe one or more claims of the patents-in-suit;

C. An Order that the effective date of FDA approval of ANDA No. 212537 be a date which is not earlier than the later of the expiration of the patents-in-suit, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

D. Preliminary and permanent injunctions enjoining Lupin and its officers, agents, attorneys and employees, and those acting in concert with them, from making, using, offering to sell, selling, or importing Lupin's Proposed Product until after the expiration of the patents-in-suit or any later expiration of exclusivity to which Plaintiffs are or become entitled;

E. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Lupin, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing the devices, compositions, formulations, and methods of use and administration claimed in the patents-in-suit, or from actively inducing or contributing to the infringement of claims of the patents-in-suit, until after the expiration of the patents-in-suit or any later expiration of exclusivity to which Plaintiffs are or become entitled;

F. A Judgment that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Lupin's Proposed Product will directly infringe, induce, and/or contribute to infringement of the patents-in-suit;

G. To the extent that Lupin has committed any acts with respect to the devices, compositions, formulations, and methods of use and administration claimed in the patents-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding Plaintiffs damages for such acts;

H. If Lupin engages in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Lupin's Proposed Product prior to the expiration of the

patents-in-suit, a Judgment awarding damages to Plaintiffs resulting from such infringement, together with interest;

I. A Judgment declaring that the patents-in-suit remain valid and enforceable;

J. A Judgment finding that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Plaintiffs their attorneys' fees incurred in this action;

K. A Judgment awarding Plaintiffs their costs and expenses incurred in this action; and

L. Such further and other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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August 20, 2019

CERTIFICATE OF SERVICE

I hereby certify that on August 26, 2019, copies of the foregoing were caused to be served upon the following in the manner indicated:

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